

Nelson, Bettie L

From: Roethig, Hans
Sent: Thursday, December 12, 2002 1:20 PM
To: 'Michael Szwaneck (402)437-4880'
Cc: Kimberly Prchal; Robert Earl; Adams, Candace R.; Feng, Shixia; Gogova, Maria; Jin, Yan; King, Valerie A.; Kinser, Robin D.; Liang, Qiwei; Mawyer, Denise T.; Mendes, Paul; Nelson, Bettie L; Oey, Jan; Roethig, Hans; Sarkar, Mohamadi; Unverdorben, Martin
Subject: RE: Controlled/uncontrolled/restricted/unrestricted
Sensitivity: Confidential

Dear Mike,
thank you very much for your proposal, which was far more than I wanted.
We had an internal discussion and agreed on the following:
Controlled smoking as defined in our short-term exposure study protocols:
Brand as defined by protocol, 7 am - 11 pm, max 30 cigs per day, max number based on acclimation day results, smoking only every 32 minutes, smoking evenly during the day;
Uncontrolled smoking as defined in the ACCORD JLI short-term exposure study:
Brand as defined by protocol, 7 am - 11 pm, up to 60 cigs per day, at any time.
Unrestricted smoking, typically in ambulatory studies:
Brand as defined by protocol, at any time, at any place, any number.
Ad lib: any brand, at any time, at any place, any number.
I hope this clarifies for all.
Please let me know if there are any problems.
Best regards
Hans

-----Original Message-----

From: Michael Szwaneck (402)437-4880 [mailto:Michael.Szwaneck@mdsps.com]
Sent: Monday, December 02, 2002 12:45 PM
To: Hans-Juergen.Roethig@pmusa.com
Cc: mohamadi.sarkar@pmusa.com; Kimberly Prchal; Robert Earl
Subject: Controlled/uncontrolled/restricted/unrestricted
Sensitivity: Confidential

Hans,

Attached as a MS-Word file is a list of the study design definitions you requested to provide consistency in all future studies. Please review to assure that I understood your request correctly.

Thanks,

Michael F. Szwaneck, Pharm D., MBA
Section Head, Protocol Development and ICFs
MDS Pharma Services - Lincoln, NE
michael.szwaneck@mdsps.com
(402) 437-4880